Effect of Iron Deficiency on skeletal muscle metabolism in HFpEF

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20027

Source
NTR

Brief title
Iron muscle

Health condition

Diabetes, obesity and hypertension, all highly present comorbidities in HFpEF, seem to drive this disease by inducing low-grade systemic inflammation which in turn induces microvascular dysfunction and activates a cascade of events. Several studies have demonstrated that HFpEF is a systemic disease that affects not only cardiac, but also peripheral muscle energy metabolism. Iron deficiency (ID) could be an important contributor in this pathophysiological process.
Iron deficiency is present in 50% of chronic HF patients. Although HFpEF was not excluded from these cohort studies, it mainly included HF with reduced ejection fraction (HFrEF).

Sponsors and support

Primary sponsor: Not aplicable
Source(s) of monetary or material Support: Not aplicable

Intervention

Outcome measures

Primary outcome

- Is skeletal muscle metabolism impaired in HFpEF patients with iron deficiency, measured using CMR spectroscopy?

Secondary outcome

- Is microvascular function impaired in HFpEF patients with iron deficiency?

- Is exercise tolerance decreased in HFpEF patients with iron deficiency?

Study description

Background summary

Diabetes, obesity and hypertension, all highly present comorbidities in HFpEF, seem to drive this disease by inducing low-grade systemic inflammation which in turn induces microvascular dysfunction and activates a cascade of events. Several studies have demonstrated that HFpEF is a systemic disease that affects not only cardiac, but also peripheral muscle energy metabolism. Iron deficiency (ID) could be an important contributor in this pathophysiological process.

Iron deficiency is present in 50% of chronic HF patients. Although HFpEF was not excluded from these cohort studies, it mainly included HF with reduced ejection fraction (HFrEF).

We hypothesize that ID is an important factor in the limitation of exercise capacity in HFpEF. Systemic low-grade inflammation does not only lead to microvascular dysfunction but also to iron deficiency. Iron deficiency has a direct effect on the muscle. Not only on the cardiac muscle but also the skeletal muscle is affected, impairing muscle contraction strength but also energy metabolism. The primary focus of this study will be delivering proof that the alterations in the muscle are more severe in HFpEF patients with ID compared to without ID.

Study objective

We hypothesize that ID is an important factor in the limitation of exercise capacity in HFpEF. Systemic low-grade inflammation does not only lead to microvascular dysfunction but also to iron deficiency. Iron deficiency has a direct effect on the muscle. Not only on the cardiac muscle but also the skeletal muscle is affected, impairing muscle contraction strength but also energy metabolism. The primary focus of this study will be delivering proof that the alterations in the muscle are more severe in HFpEF patients with ID compared to without ID.

Study design

Not aplicable

Intervention

o Measurement of PCR recovery time using MR spectroscopy

- Microvascular function

o Glycocalyx thickness (um)

o Heat induced hyperaemic response (% skin hyperaemic response)

- Exercise tolerance

o 6 minute walk test distance (m)

o maximum exercise capacity (METs on exercise test)

Contacts

Public
Postbus 5800
Arantxa Barandiaran
Maastricht University Medical Centre, Department of Cardiology

Maastricht 6202 AZ
The Netherlands
+31(0)43-3871148
Scientific
Postbus 5800
Arantxa Barandiaran
Maastricht University Medical Centre, Department of Cardiology

Maastricht 6202 AZ
The Netherlands
+31(0)43-3871148

Eligibility criteria

Inclusion criteria

• HFpEF: according to the ESC guidelines

(1) Signs and/or symptoms of heart failure,

(2) LVEF ≥ 50%,

(3) Elevated levels of natriuretic peptide (NT-proBNP > 125 pg/ml
~ 15 pmol/L)

(4) one of the following additional criteria

a) Relevant structural heart disease; LV hypertrophy, (LVmass index > 95 g/m2 in women, or >115 g/m2 in men) and/or LA enlargement (LA volume index >34 l/m2)

b) Diastolic dysfunction (E/e' ≥ 13, mean e' septal and lateral wall < 9 cm/s)

• Iron deficiency: serum ferritin < 100 µg/L or serum ferritin between 100-299 µg/L in combination with a transferrin saturation < 20%.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Reproductive age women

- Any iron supplement (oral, iv) during the last 6 months prior to inclusion

- Any chemotherapy in last year

- Significant peripheral artery disease

- Contraindication for CMR

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	79
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55673
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7059
NTR-old	NTR7297
CCMO	NL65600.068.18
OMON	NL-OMON55673

Study results

Summary results
Not aplicable